DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

AMENDED CHARTER

RECOMBINANT DNA ADVISORY COMMITTEE

PURPOSE

The purpose of the Recombinant DNA Advisory Committee (Committee) is to provide advice and recommendations to the Director of the National Institutes of Health (NIH) on (1) the conduct and oversight of research involving recombinant DN,4, including the content and implementation of the *NIH Guidelines for Research Involving Recombinant DNA Molecules,* as amended *(NIH Guidelines)*, and (2) other NIH activities pertinent to recombinant DNA technology. There will be a continuing need for the Committee to serve these functions so long as the NIH supports activities involving recombinant DNA.

AUTHORITY

42 U.S.C. 282(b)(6), section 402(b)(6) of the Public Health Service Act, as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

FUNCTION

The Committee shall advise the Director, NIH, on all aspects of research involving the use of recombinant DNA and on developments in recombinant DNA technology. More specific functions of the committee are set forth in Section IV-C-2 of the *NIH Guidelines.* The Committee is responsible for carrying out the functions set forth in the *NIH Guidelines,* as well as any others assigned under its charter or by the Secretary of Health and Human Services or the Director, NIH.

As necessary, the Committee and its subcommittees may call upon special consultants; assemble ad hoc working groups and convene conferences, workshops and other activities.

STRUCTURE

The Committee shall consist of up to 21 voting members, including the Chair, appointed by the Director, NIH. A majority of the voting members must be knowledgeable in relevant scientific fields, e.g. molecular genetics, molecular biology, recombinant DNA research, including clinical gene transfer research. At least four members of the Committee must be persons knowledgeable in fields such as public health, laboratory safety, occupational health, protection of human subjects of research, the environment, ethics, law, public attitudes or related fields.

There may be nonvoting representatives from each of the following Federal agencies:

Department of Agriculture
Department of Commerce
Department of Defense
Department of Health and Human Services
- -Centers for Disease Control and Prevention
- -National Institute for Occupational Safety and Health
- -Food and Drug Administration
- -Center for Biologics Evaluation and Research
- -Office for Human Research Protections
Department of Energy
Department of Interior
Department of Justice
Department of Labor
Department of State
Department of Transportation
Environmental Protection Agency
Executive Office of the President
National Aeronautics and Space Administration
National Science Foundation
Nuclear Regulatory Commission
U.S. Arms Control and Disarmament Agency
Department of Veterans Affairs

As necessary, standing and ad hoc subcommittees composed of members of the parent Committee and, as appropriate, consultants with relevant expertise may be called upon to perform specific functions within the Committee's jurisdiction. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings. All subcommittees shall report to the parent Committee.

A member of one subcommittee may serve as a voting member of other subcommittees when that member's expertise is required. However, that member shall not be counted in determining the presence of a quorum.

Members shall be invited to serve for overlapping terms of two to four years; terms of more than two years are contingent upon the renewal of the Committee by appropriate action prior to its expiration. A member may serve after the expiration of the member's term until a successor has been appointed.

Management and support services for the Committee shall be provided by the Office of Biotechnology Activities, Office of the Director, NIH.

MEETINGS

Meetings shall be held approximately four times a year at the call of the Designated Federal Official who shall also approve the agenda. The Designated Federal Official shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Secretary of Health and Human Services. Notice of all meetings shall be given to the public.

Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and Departmental policies.

QUORUM

A quorum for the Committee and each of its subcommittees shall consist of a majority of the appointed members eligible to vote. The nonvoting agency representatives shall not be counted in calculating the quorum. Of the voting members any who are disqualified from participating in an action on a particular issue, e.g., because of a conflict of interest, shall not be counted in calculating the quorum. All votes relating to any review or recommendation by the Committee shall be open to the public unless the meeting has been closed to the public in accordance with 5 U.S.C. 552b(c).

COMPENSATION

Members shall be paid at the rate of $200 per day for each meeting day, plus per diem and travel expenses as authorized by section 5703, Title 5 U.S.C., as amended, for persons in the Government service employed intermittently. Members who are officers or employees of the United States Government shall not receive compensation for service on the Committee.

ANNUAL COST ESTIMATE

Estimated annual costs for operating the Committee, including compensation and travel expenses for members but excluding staff support is $395,480. The estimated annual person-years of staff support is 6.0 at an estimated cost of $644.181.

REPORTS

In the event a portion of a meeting is closed to the public, a report shall be prepared which shall contain, at a minimum, a list of the members and their business addresses, the Committee's functions, dates and places of meetings, and a summary of the Committee's activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

TERMINATION DATE

Unless renewed by appropriate action prior to its expiration, the Charter for the Recombinant DNA Advisory Committee shall expire on June 30, 2003.

APPROVED

1/11/02
Date

Ruth L. Kirschstein
Acting Director, NIH